K050706

Page 1 of 2

APR 15 2005

510(k) NOTIFICATION SUMMARY

THE HARMONY™ PORT SYSTEM

SUBMITTER:	Spinal Concepts, Inc.
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	Noah Bartsch Specialist, Regulatory Affairs Telephone: 512.533.1840 Fax: 512.918.2784
DATE:	March 16, 2005
TRADE NAME:	The Harmony™ Port System
COMMON NAME:	Surgical Retractor
CLASSIFICATION NAME:	Self-Retaining Retractor for Neurosurgery
CLASSIFICATION REFERENCE:	21 CFR § 882.4800
PREDICATE DEVICE:	The Bright Medical Dilation Retractor System manufactured by Bright Medical Instruments, K992898, cleared October 21, 1999.
DEVICE DESCRIPTION:	The Harmony Port System includes the Harmony Port, which provides surgical exposure during minimally invasive procedures, along with accessory instruments designed to facilitate the use of the Port and rigidly fix the system during use.
INDICATIONS:	To provide a self-locking mechanism to hold the edges of a wound open and allow for surgical exposure during general use and neurosurgical procedures.
COMPARISON TO PREDICATE DEVICE:	The Harmony Port System has the same intended use, is manufactured from similar materials using similar processes, and is similar in design when compared to the predicate device.

K050706

PERFORMANCE DATA:	The results of non-clinical testing and evaluation demonstrate that the device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Mr. Noah Bartsch
Specialist, Regulatory Affairs
Spinal Concepts, Inc.
5301 Riata Park Court, Building F
Austin, Texas 78727

Re: K050706
Trade/Device Name: Harmony™ Port System
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: II
Product Code: GZT
Dated: March 16, 2005
Received: March 18, 2005

Dear Mr. Bartsch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050706

Indications for Use

510(k) Number (if known):

Device Name:

Harmony™ Port System

Indications for Use:

To provide a self-locking mechanism to hold the edges of a wound open and allow for surgical exposure during general use and neurosurgical procedures.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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